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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/787,840	07/06/2001	Mark Leslie Smythe	4050.001100	8048
27683	7590	05/25/2006	EXAMINER	
HAYNES AND BOONE, LLP 901 MAIN STREET, SUITE 3100 DALLAS, TX 75202			KAM, CHIH MIN	
			ART UNIT	PAPER NUMBER
			1656	
DATE MAILED: 05/25/2006				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/787,840

Applicant(s)

SMYTHE ET AL.

Examiner

Chih-Min Kam

Art Unit

1656

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 December 2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-31,35,39 and 40 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-31,35,39 and 40 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 22 March 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Status of the Claims

1. Claims 1-31, 35 and 39-40 are pending.

Applicant's amendment filed December 28, 2005 is acknowledged, and applicants' response has been fully considered. Claims 1-31 and 35 have been amended, claims 32-34 have been cancelled, and new claims 39-40 have been added. Therefore, claims 1-31, 35 and 39-40 are examined.

Oath/Declaration

2. A new oath or declaration filed on December 28, 2005 is still defective because it listed the foreign priority document, AU PP6165 under 35 U.S.C. 120, where the foreign priority document should be listed under 119 (a)-(d).

Withdrawn Informalities

3. The previous objection of the specification regarding "SEQ ID NO:" not be cited for amino acid sequences is withdrawn in view of applicant's amendment to the specification filed October 20, 2003, and applicant's response at page 16 in the amendment filed December 28, 2005.

Withdrawn-Claim Objections

4. The previous objection of claims 1, 11, 16, 30 and 35 is withdrawn in view of applicant's amendment to the claim, and applicant's response at pages 16-17 in the amendment filed December 28, 2005.

Withdrawn Claim Rejections - 35 U.S.C. § 112

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5. The previous rejection of claims 4, 7, 12-15, 17-29 and 35 under 35 U.S.C. § 112, second paragraph (see paragraphs 8-14 in the previous Office Action dated 7/28/05), is withdrawn in view of applicant's amendment to the claim, and applicant's response at pages 17-19 in the amendment filed December 28, 2005.

Withdrawn Claim Rejections - 35 USC § 102

6. The previous rejection of claims 1-3, 6-8 and 14 under 35 U.S.C. 102(b) as being anticipated by Bodanszky (U. S. Patent 3,704,246), is withdrawn in view of applicant's amendment to the claim, and applicant's response at page 20 in the amendment filed December 28, 2005.

7. The previous rejection of claims 1-3, 6-8 and 14 under 35 U.S.C. 102(b) as being anticipated by Ehrlich *et al.* (J. Org. Chem. 61, 8831-8838 (1996)), is withdrawn in view of applicant's amendment to the claim, and applicant's response at pages 20-23 in the amendment filed December 28, 2005.

Withdrawn Claim Rejections-Obviousness Type Double Patenting

8. The previous rejection of claims 1-21, 23, 30, 31 and 35 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 8-19, 32-35, 39, 40 and 46-52 of co-pending application 09/806,036, is withdrawn in view of applicant's terminal disclaimer, and applicant's response at pages 23-24 in the amendment filed December 28, 2005.

Claim Objection

9. Claim 7 is objected to because of the use of the term "the XH group is at position 2 or 3 General Formula II", which should insert the word "in" before "General Formula II".
Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claims 1-31, 35 and 39-40 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

11. Claims 1-16 and 35 are indefinite because the claim recites the step of linking a cyclic aromatic auxiliary compound of General Formula II to a primary amine nitrogen atom to form a secondary amine, and converting the secondary amine to an amide, however, it does not indicate which molecule the primary amine nitrogen atom belongs to, and how the linear or cyclic peptide, the C-terminal modified peptide, or on-resin cyclization of a peptide molecule is synthesized via the auxiliary compound. Claims 2-13, 15, 16 and 35 are included in the rejection because they are dependent on rejected claims and do not correct the deficiency of the claim from which they depend.

Response to Arguments

Applicants indicate claims 1 and 14 have been amended to recite “a primary amine nitrogen atom to form a secondary amine” (page 17 of the response).

Applicants’ response has been considered, however, the arguments are not found persuasive because the claim does not indicate how the linear or cyclic peptide, the C-terminal modified peptide, or on-resin cyclization of a peptide molecule is synthesized via the auxiliary compound (see paragraph 11 above).

12. Claim 6 is indefinite because the claim has the same scope as claim 1.

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13. Claims 17-21, 23 and 39 are indefinite as to how the auxiliary compound assists the synthesis of a cyclic peptide since the claim only recites the steps of linking an auxiliary compound to a selected primary amine of the linear peptide, activating a selected carboxylic acid to effect cyclization, the claim does not indicate how the cyclic peptide is formed via the auxiliary compound. Claims 18-21, 23 and 39 are included in the rejection because they are dependent on rejected claims and do not correct the deficiency of the claim from which they depend.

14. Claims 20 and 39 are indefinite as to where in the linear peptide the solid support is connected to.

15. Claims 22 and 40 are indefinite as to how the auxiliary compound assists the synthesis of a large peptide since the claim only recites the steps of linking an auxiliary compound to the primary amine of the first peptide fragment, activating the C-terminal carboxylic acid of the second peptide fragment, adding the second peptide fragment to the first peptide fragment to form a peptide bond, the claim does not indicate how the peptide is formed via the auxiliary compound. Claim 40 is included in the rejection because it is dependent on a rejected claim and does not correct the deficiency of the claim from which it depends. Claim 22 is also indefinite as to how the large peptide is formed from the rest of peptide fragments.

16. Claims 24 and 25 are indefinite because of the use of the term “a) linking an auxiliary compound as defined in claim 1 to one or more nitrogen atoms in peptide bonds of a peptide linked to a solid support”. The term cited renders the claim indefinite, it is not clear which peptide the peptide of step a) refers to, e.g., which peptide, the peptide of step a) or the complete peptide of step b), is a difficult peptide sequence? Claim 25 is included in the rejection because

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it is dependent on a rejected claim and does not correct the deficiency of the claim from which it depends.

17. Claims 26-29 are indefinite as to how the auxiliary compound is involved in the backbone linkage for synthesis of a linear peptide since the claim recites linking an auxiliary compound to an alpha-nitrogen of an amino acid in the peptide to a solid support, and assembling the linear peptide using standard solid phase synthesis. Claims 27-29 are included in the rejection because they are dependent on rejected claims and do not correct the deficiency of the claim from which they depend.

18. Claims 27 and 28 are indefinite as to the carboxylic acid group of the C-terminal amino acid residue is replaced by a functional group, it is not clear which step (e.g., step a), b), c) or d)) the carboxylic acid is replaced?

Response to Arguments

Applicants indicate claims 27 and 28 have been amended to clarify the functional may be selected from the group consisting of an ester, an alkylalcohol, an acetal, or an amide group. (page 19 of the response).

Applicants' response has been considered, however, the arguments are not found persuasive because the claim does not indicate when this replacing step occurs.

19. Claim 28 recites the limitation "the functional group" in line 2. There is insufficient antecedent basis for this limitation in the claim.

20. Claims 30-31 are indefinite as to how the auxiliary compound is involved in on resin cyclization of a linear peptide since the claim recites linking an auxiliary compound to an alpha-nitrogen of an amino acid residue in the desired peptide to a solid support, and synthesizing the

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linear peptide using standard solid phase synthesis. Claim 31 is included in the rejection because it is dependent on a rejected claim and does not correct the deficiency of the claim from which it depends.

Conclusion

21. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (571) 272-0948. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Kerr can be reached at 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Chih-Min Kam, Ph. D.
Patent Examiner



**CHIH-MIN KAM
PATENT EXAMINER**

CMK

May 19, 2006